UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA
ex rel. JEFFREY J. BIERMAN,

Plaintiff,

v. CIVIL ACTION NO.:
05-10557-EFH

ORTHOFIX INTERNATIONAL, N.V., ET AL.,

Defendants.

* *

UNITED STATES OF AMERICA
ex rel. MARCUS LAUGHLIN,

Plaintiff,

v. (Formerly CIVIL ACTION
NO.: 08-11336-JLT)

ORTHOFIX INTERNATIONAL, N.V., ET AL.,

Defendants.

* *

MEMORANDUM AND ORDER

December 8, 2010

HARRINGTON, S.D.J.

Qui tam relator, Jeffrey J. Bierman, brings this suit on behalf of the United States of America and various state and local governments against defendants, medical device

manufacturers, alleging violations of the federal False Claims Act, 31 U.S.C. § 3729-3733, ("FCA") and analogous local and state statutes. Defendants move to dismiss Bierman's Second Amended Complaint contending that it fails to state a claim upon which relief can be granted under Fed. R. Civ. P. 12(b)(6) and fails to plead allegations of fraud with the particularity required by Fed. R. Civ. P. 9(b). The Court denies the defendants' motions.

Background.

The plaintiff/relator, Jeffrey J. Bierman, ("the relator") is the co-owner of a business that provides medical billing and related services to health care providers. The defendants are the sole manufacturers and suppliers in the United States of a medical device called a non-invasive bone growth stimulator.[1] Bone growth stimulators are light weight, battery operated devices which emit weak electrical currents or ultrasonic waves to facilitate healing in patients who have undergone spinal surgery or have non-healing fractures. Bone growth stimulators are covered by Medicare.

The stimulators are classified under Medicare regulations as "inexpensive or other routinely purchased" durable medical equipment. Medicare pays for medical equipment under such a classification on a monthly rental or purchase basis according to a fee schedule. While the fee schedule varies from state to state, the purchase price for the stimulators is approximately ten times more than their monthly rental price. Therefore, a device would have to be used for a period of ten months or more for the accrued rental payments to equal the purchase price. Beneficiaries are responsible for a twenty (20%) percent copayment for the device and Medicare pays the remaining balance.

[1] The devices are also known as osteogenesis stimulators.

In order to receive billing privileges from Medicare, a supplier of medical equipment must submit, and renew every three years, a Medicare Enrollment Application. The application requires the supplier to certify that it will abide by applicable Medicare laws, regulations and program instructions.[2] One such regulation is the so-called Supplier Standard Regulation, 42 C.F.R. § 424.57(c). The Supplier Standard Regulation, among other things, requires a supplier to "advise beneficiaries that they may either rent or purchase inexpensive or routinely purchased durable medical equipment."

After a supplier received billing privileges, it may submit claims for reimbursement to the Centers for Medicare and Medicaid Services. To be reimbursed for a claim, a supplier must submit a Health Insurance Claim Form, FORM CMS-1500 ("1500 Form") and a Certificate of Medical Necessity ("CMN"). The 1500 Form requires the supplier to indicate whether the item is being billed as a rental item (signified by the modifier RR), a purchase of new equipment (signified by the modifier NU), or a purchase of used equipment (signified by the modifier UE). The supplier must also make an express written certification on the 1500 Form that "the services shown on the form were medically indicated and necessary to the health of the patient."

The CMN, on the other hand, must be signed by the ordering physician, a physician employee, or a non-physician clinician (such as a home health nurse or physical therapist). The signature attests that the medical necessity information in the CMN is true, accurate and

[2] The Medicare Enrollment Application includes the following certification language:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier ... I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law,) and on the supplier's compliance with all applicable conditions of participation by Medicare.

complete. The CMN also requires the physician, physician employee or clinician to indicate the length of time the physician expects the patient to require use of the ordered item by placing a number in the section marked: "est. length of need (# of months)." If the physician expects that the patient will require the item for the duration of his or her life, the physician must enter the code number "99."

The relator alleges that, between 1993 and 2010, the defendants knowingly submitted or caused to be submitted false claims for Medicare reimbursement and made false statements in an effort to get false claims paid and approved by Medicare. The relator alleges that patients typically require the bone-growth stimulators for a period of between three and six months and that the bone-growth stimulators are programmed to automatically deactivate after nine months.[3] The relator asserts that, therefore, no rational patient would ever choose the purchase option and that no claim for purchase could ever be supported by medical necessity. The relator alleges, however, that the defendants have routinely billed the devices to Medicare as purchase items. Attached to the complaint is a schedule of claims submitted to Medicare by the defendants for the period of 1993 through 2006. The schedule shows that every claim submitted contained the modifier "NU," indicating a purchase of a new device.

The relator alleges that the "medical necessity" section of the CMN is often completed by a physician's clerical assistant and the CMN is signed off by the physician. These clerical assistants typically rely on the equipment suppliers' representatives for advice about how the CMN should be completed in order to ensure that claims will be processed and paid by Medicare.

[3] The devices manufactured by defendant Smith & Nephew, Inc. do not automatically deactivate after nine months but are equipped with a non-replaceable and non-rechargeable battery which lasts only about five months.

Between March 2007 and December 2008, the relator, as a representative of a company purporting to supply medical devices and provide billing services to physicians, had numerous conversations with representatives of the defendants about purchasing the stimulators and other medical devices and supplies from them. The relator alleges that he was routinely told by those representatives that the stimulators were only available for purchase and could not be rented.

In or about January 2005, an equipment supplier client of the relator forwarded to the relator a completed prescription and a CMN for a stimulator for a Medicare patient. In the section marked "est. length of need (# of months)," the code "99" had been entered indicating that the patient would require the item for the duration of his or her life. The client indicated to the relator that doctors filled in code "99" despite the fact that the patient did not need the device for his or her lifetime because "in his (doctor's) mind he knows it's a purchase only item and it's not a rental item." The client stated that, "this is just what the manufacturers are telling me … they do these all the time … they tell me that they don't rent them they purchase them … one person gets them and that's it." The relator alleges that the defendants routinely instruct doctors to include the code "99" on the CMN or otherwise specify a number of months that will support payment for the item as a purchase.

Suppliers must also certify in their Medicare Enrollment Applications that they have complied with the Federal Anti-Kickback Statute, 42 U.S.C.1320a-7b(b). Relator alleges that certain defendants violated the Anti-Kickback Statute by (1) providing doctors with free stimulators in exchange for Medicare business; (2) routinely paying commissions to independent sales agents, including commissions based on a percentage of the Medicare billings that the

agents generate; and (3) giving third party suppliers volume discounts on purchases of the stimulators, without including those discounts on invoices.

Discussion.

The FCA, 31 U.S.C. §§ 3729-3733, prohibits false or fraudulent claims for payment to the Federal government. Under the FCA, liability attaches to a "false or fraudulent claim for payment," or a "false record or statement [made] to get a false or fraudulent claim paid," 31 U.S.C. § 3729(a)(1)-(a)(2) (2008), amended by 31 U.S.C. § 3729(a) (2009). The *qui tam* provisions of the FCA allow a private citizen (called a relator) to bring a civil claim under the statute "for the person and for the United States Government . . . in the name of the Government." 31 U.S.C. § 3730(b)(1).

The relator sets forth four theories under which he claims the defendants violated § 3729(a)(1) and § 3729(a)(2) of the FCA and analogous state and local statutes. The relator alleges that the defendants (1) made false express certifications of compliance with the Supplier Standard Regulation; (2) made false implied certifications of compliance with the Supplier Standard Regulation; (3) submitted false Certificates of Medical Necessity with its claims for payment; and (4) made false express certifications of compliance with the Anti-Kickback Statute. The defendants contend that these theories do not constitute violations of the FCA and that they are not pled with sufficient particularity under Fed. R. Civ. P. 9(b).

a. Legal basis for violation of FCA.

Under the first alleged theory of liability, the relator contends that defendants violated the FCA by falsely certifying that they would abide by applicable Medicare laws, regulations and program instructions in their Medicare Enrollment Applications. When applying for billing

privileges, suppliers must certify the following:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law,) and on the supplier's compliance with all applicable conditions of participation by Medicare.

One such Medicare regulation is Supplier Standard Regulation Number 5, which requires a supplier to "advise beneficiaries that they may either rent or purchase inexpensive or routinely purchased durable medical equipment." 42 C.F.R. § 424.57(c)(5). Relator asserts that the defendants violated the FCA by certifying compliance with all applicable conditions of Medicare participation, knowing that they would not inform patients of the rental option as required by Supplier Standard Regulation Number 5.[4] To state a claim under 31 U.S.C. § 3729(a)(1) and (a)(2) a relator must, *inter alia*, allege that a false claim or statement was made.[5] The defendants assert that no falsity occurred because the certification contained in the application is too broad to constitute an express certification of compliance with Supplier Standard Regulation Number 5.

In support of their position, the defendants cite to United States ex rel. Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123 (D. Mass. 2010), which held that broad language in a state

[4] Contrary to the defendants' contention, the Court does not understand this theory of liability to rest on the proposition that the defendants are required to rent all stimulators. Rather, the theory is based on the requirement that the defendants provide a rental option to beneficiaries.

[5] 31 U.S.C. § 3729(a) imposes liability on any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government. . . .

Medicare Enrollment Application, requiring compliance with "all applicable state and federal laws," was insufficient to constitute an express certification of compliance with state and Federal Anti-Kickback Statutes. Id. at 136. The defendants argue that, like the state certification in Westmoreland, the certification here does not explicitly mention the Supplier Standard Regulation Number 5 and is otherwise too broad to serve as the basis for an FCA action.

The certification at issue here, however, is far more narrow than the state certification at issue in Westmoreland. The certification here does not require general compliance with "state and federal laws" but rather, compliance with "Medicare . . . regulations" and notes that payment is conditioned on the "supplier's compliance with all applicable *conditions of participation* by Medicare." While the Supplier Standard Regulation Number 5 is not explicitly listed in the certification, it is such an applicable condition of participation by Medicare and is explicitly labeled as a condition of participation in the regulations. Part 424 of Title 42 is headed "Conditions for Medicare Payment" and § 424.57 is labeled "issuance of . . . supplier billing privileges." Furthermore subsection (c) is entitled "Application certification standards" and states that "[t]he supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards," which includes Supplier Standard Regulation Number 5. The certification, therefore, directly concerns the regulation and the regulation directly concerns the certification. The defendants' argument that each specific regulation must be listed in order to constitute an express certification amounts to a contention that the certification at issue covers only the Anti-Kickback Statute and the Stark law.[6] The Court declines to adopt such a narrow position.

[6] The complaint further alleges that "[t]he Medicare Enrollment Application includes an abbreviated version of the Supplier Standards, cites 42 C.F.R. §424.57(c) and states on its cover page that every applicant must meet and maintain these enrollment standards."

Westmoreland's holding on this issue was premised on the idea that "broad liability conflicts with the principle that not any false statement imposes liability under the False Claims Act, but only those which are material and would have 'led the government to make a payment which it would not otherwise have made.'" Westmoreland, 707 F. Supp. 2d at 137 (quoting United States ex. rel. Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1218-19 (10th Cir. 2008)). An applicant that failed to certify that it would comply with Supplier Standard Regulation Number 5 would not be allowed to participate in the Medicare billing process. Thus, a false certification would lead the government to make a payment it would not otherwise have made.

Furthermore, the Supplier Standard Regulation Number 5 is not, as the defendants suggest, a trivial regulation whose enforcement by way of the FCA would open the flood gates to tort liability. It is not, for instance, a regulation which apart from the certification is unrelated to the Medicare billing process. Rather, the application of the regulation directly affects the amount of money paid by the government for reimbursement claims. Accordingly, a supplier violates the FCA if it certifies compliance with applicable conditions of participation by Medicare, knowing at the time of certification that it would not abide by Supplier Standard Regulation Number 5.

The defendants do not challenge any other elements of the claims under this theory of liability and the Court concludes that, if pled with particularity, the allegations with respect to this theory can serve as both a violation of section 3729(a)(1) and 3729(a)(2). The false express certification constitute both a false claim for payment under section 3729(a)(1) and a false statement made to get a false claim paid under section 3729(a)(2).[7] See Westmoreland, 707 F.

[7] Congress recently revised subsection (a)(1) and (a)(2). See The Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4(a), 123 Stat. 1617, 1621 (2009) (now codified at

Supp. 2d at 134-35 (holding that a false certification in a Medicare Enrollment Application constitutes a violation of section 3729(a)(1) as long as the certification was knowingly false when made); United States ex rel. Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1168 (10th Cir. 2010) ("express-false-certification claims may presumably arise under any subsection of § 3729(a)").

b. Particularity requirement of Fed. R Civ. P. 9(b).

Defendants contend that the complaint fails to plead the allegations of fraud with particularity as required by Fed. R. Civ. P. 9(b). The United States Court of Appeals for the First Circuit has held that the heightened pleading requirements of Fed. R. Civ. P. 9(b) for allegations of fraud apply to claims brought under 31 U.S.C. §§ 3729(a)(1) and 3729(a)(2). See United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir. 2009).

Rule 9(b) requires a party alleging fraud or mistake to state with particularity the circumstances constituting the fraud or mistake. Fed. R. Civ. P. 9(b). This standard requires that the complaint include details which identify a particular false claim including "the time, place, and content of an alleged false representation." Gagne, 565 F.3d at 45 (internal quotations omitted); see United States ex rel. Karvelas v. Melrose-Wakefield Hospital, 360 F.3d 220 (1st Cir. 2004).

The Court concludes that the Second Amended Complaint is sufficiently particular to pass muster under Rule 9(b). The relator alleges that the defendants submitted initial Medicare Enrollment Applications to the government in or about December of 2000 and the complaint provides details about the content of those applications. The complaint also includes a schedule

31 U.S.C. § 3729(a)(1)(A) and (a)(1)(B)). The relator pleads the amended versions of (a)(1) and (a)(2) as Counts III and IV. The defendants do not separately challenge these counts.

of Medicare claims for reimbursement submitted by each defendant for a number of specified years.[8] That schedule includes the number of claims allowed and denied by Medicare and the amounts that were submitted and paid. Since the submission of the certification in the Medicare Enrollment Application every three years is a prerequisite to submitting claims for reimbursement, see 42 C.F.R. § 454.506 and § 424.57(g), the complaint contains sufficient basis to support the allegation that the certification was submitted to the government by each defendant. The complaint, therefore, sufficiently identifies the particular claims that were submitted.

The complaint further alleges facts indicating that the stimulators can only be used for up to nine months, that they are usually required for only three to six months, and that their purchase price is roughly ten times their monthly rental price. The schedule of reimbursed Medicare claims, however, indicates that every claim submitted by the defendants over a number of years was for a purchase item. A separate table attached to the complaint lists specific claims by the defendants, the dates of those claims and the amount allowed for reimbursement. Each claim in the table was reimbursed by Medicare as a purchase item. Since no rational beneficiary would ever pay for more than the nine month rental price, there is a sufficient basis to infer that beneficiaries were never offered the rental option.

[8] The complaint refers to defendants Orthofix International N.V. and its wholly-owned subsidiary, Orthofix, Inc., collectively as "Orthofix." The complaint also refers to defendants Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., and Bioelectron, Inc collectively as "EBI." EBI, L.P. is a wholly owned subsidiary of Biomet, Inc. EBI Holdings, Inc. and EBI Medical Systems, Inc. are general and limited partners of EBI, L.P. respectively. The complaint further refers to DJO Incorporated and Reable Therapeutics, Inc. collectively as "DJO." Reable Therapeutics, Inc. and DJO Incorporated merged in 2007. The schedule of claims attached to the complaint includes claims from at least one company from each group of related companies.

The complaint further sets forth allegations that the defendants made concerted efforts to maintain the stimulators as a purchase-only items. It alleges numerous instances in which the relator, acting as a billing service provider, was told by the defendants' representative, who are identified in the complaint by reference to their corporate title, that the stimulators were not available for rent. The schedule of reimbursed claims allows for a reasonable inference that the defendants routinely failed to inform beneficiaries of the rental option over a number of years. It states specific instances in which certain representatives of the defendants admitted knowledge of and noncompliance with the Supplier Standard Regulation Number 5. It also identifies the large monetary incentive the defendants had to provide the stimulators as purchase-only items. These alleged facts allow for a fair inference that the defendants knew that they would not comply with the Supplier Standard Regulation Number 5 when they certified and submitted the Medicare Enrollment Applications. Accordingly, the complaint alleges that the defendants submitted a false claim or statement with sufficient particularity under Rule 9(b).[9]

Since the Complaint properly alleges a violation of § 3729(a)(1) and § 3729(a)(2) under the express certification theory of liability and properly pleads the allegations with sufficient particularity, the Court need not consider the defendants' alternate theories of liability. The Court also does not consider arguments with respect to the municipal or state claims or the relationships between corporate entities. Those arguments shall be considered on a motion for summary judgment at the close of discovery.

[9] The Court holds that the complaint complies with the stringent pleading standard set forth above, which requires details as to particular alleged false claims. The Court, therefore, need not consider whether the more relaxed pleading standard articulated in United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720 (1st Cir. 2007) and United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13 (1st Cir. 2009) applies to the relator's case.

The defendants' motions to dismiss (Docket Numbers 128, 130, 132, 133, and 136) are, hereby, DENIED.

SO ORDERED.

/s/ Edward F. Harrington
EDWARD F. HARRINGTON
United States Senior District Judge